SEP 11 2002

Sound Surgical Technologies LLC

Creating the Perfect Wave

1300 Plaza Court North, Suite 103, Lafayette, CO 80026 tel 303.926.8608 fax 303.926.8615

510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K022051

Submitter

Sound Surgical Technologies LLC
1300 Plaza Court North, #103
Lafayette, Colorado 80026

Contact Person

William W. Cimino, Ph.D. 303-926-8608 (TEL)
303-926-8615 (FAX)

Date Prepared

June 21, 2002

Proprietary Name

SoundVASER System

Common, Usual, or Classification Name

Instrument, Ultrasonic Surgical

Classification

Class: Class II
Panel: 21 CFR 878, General and Plastic Surgery
Product Code: LFL, MUU

Predicate Devices

The SoundVASER System is similar in technical design and operation to other surgical systems that utilize ultrasonic frequency vibrating instruments for soft fragmentation and aspiration that the FDA has determined to be substantially equivalent to pre-amendment devices as depicted below:

- Sound Surgical Technologies, The SoundVASER System, K991791
- Sound Surgical Technologies, The SoundVASER System, K993868
- Mentor Corporation, The Contour Genesis System, K970471
- Mentor Corporation, The Contour Genesis System, K983065
- Mentor Corporation, The Contour Genesis System, K004005

Device Description

The SoundVASER System is comprised of an ultrasonic generator (110/120 and 220/240 VAC, 50 & 60 Hz), an ultrasonic surgical handpiece with an ultrasonic surgical probe, and a suction/irrigation subsystem. The ultrasonic surgical handpiece converts electrical energy supplied by the ultrasonic generator into vibratory motion. The vibratory motion is applied to the ultrasonic surgical probe that is attached to the ultrasonic surgical handpiece. The vibratory motion at the tip of the ultrasonic surgical probe fragments and emulsifies contacted soft tissues. The suction/irrigation subsystem is used to remove the fragmented tissues.

Intended Use

The SoundVASER System is indicated for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

The SoundVASER is indicated for use when the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring is desired.

Summary of Technological Characteristics

The SoundVASER System is similar with regard to design, operation, materials, methods of sterilization, and intended use to the predicate devices

indicated above. Therefore, no new safety or efficacy issues are created and the SoundVASER System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2002

Sound Surgical Technologies LLC
William W. Cimino, Ph.D.
1300 Plaza Court, North, #103
Lafayette, Colorado 80026

Re: K022051
Trade/Device Name: Soundvaser System
Regulation Number: 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: June21, 2002
Received: June24, 2002

Dear Dr. Cimino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022051

Device Name: The SoundVASER System

Indications for Use:

The SoundVASER System is indicated for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

The SoundVASER System is indicated for use when the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring is desired.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022051

Prescription Use ✓ Over-The-Counter Use ___
(per 2.1 CFR 801.109)
(Optional Format 1-2-96)